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Art Unit 1648

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/550,580; § 371(c) Date: September 23, 2005

For: HIV-Peptide-Carrier-Conjugates

Inventors: BACHMANN et al. Our Ref: 1700.0610001/BJD/WBC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Reply to Restriction Requirement and Election of Species; and
- 2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono
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BJD/WBC:cpn Enclosures 648179_1.DOC

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In re application of:

Martin F. BACHMANN et al.

Appl. No.: 10/550,580

§ 371(c) Date: September 23, 2005

For: HIV-Peptide-Carrier-Conjugates

Confirmation No.: 8355

Art Unit: 1648

Examiner: KINSEY, Nicole

Atty. Docket: 1700.0610001/BJD/WBC

Reply to Restriction Requirement with Election of Species

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated February 9, 2007, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 1, 2, 4, 6-12, 14, 15, 17-19, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111. In reply to the requirement for an election of species, Applicants hereby provisionally elect the following species:

- 1. Virus-like particle comprising of recombinant proteins of RNA-phages of claim 21(k);
- 2. Antigen comprising of the amino acid sequence of SEQ ID NO:71 of claim 19(a);
- 3. Antigens comprising the amino acid sequence of SEQ ID NO:72 of claim 18(a) and the amino acid sequence of SEQ ID NO:85 of claim 18(b);
 - 4. Virus particle comprising of bacteriophage $Q\beta$ of claim 24(a); and

5. Immunostimulatory nucleic acid comprising of deoxyribonucleic acids of claim 27 (b).

Presently, claims 1, 2, 6, 8, 10, 12, 14, 15, 17-19, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 read on the elected species. The aforementioned elections of restriction group and species are made without prejudice to or disclaimer of the other claims or inventions disclosed, and are made with traverse.

Applicants respectfully assert that division of the present claims is improper under PCT Rules 13.1 and 13.2. Under PCT Rule 13.2, an alleged group of inventions claimed in a single application fulfill the unity of invention requirement of PCT Rule 13.1 when they share one or more of the same or corresponding special technical features. The phrase "special technical features," means "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." PCT Rule 13.2. Additionally, the U.S. Patent and Trademark Office regulations provide guidance to Examiners in regard to unity of invention:

- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories: . . .
 - (2) A product and process of use of said product; . . .

37 C.F.R. § 1.475(b)(2).

Furthermore, the PCT International Search and Preliminary Examination Guidelines provide:

(c)(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in

Atty. Dkt. No. 1700.0610001/BJD/WBC

respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention . . . Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

PCT International Search and Preliminary Examination Guidelines, Part III, Chapter 10.

The following examples are also provided:

Example 1

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

Example 15

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a

carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

Id. at Chapter 10.

Here, Groups I and II possess unity of invention because all of their respective claims contain reference to the special technical feature, i.e., a composition comprising a virus-like particle; at least one immunostimulatory substance; and at least one antigen or antigenic determinant, a required limitation, and these claims represent a product and a use of said product. Thus, Groups I and II should be examined together.

Furthermore, the election of Restriction Group I is made with traverse because all the claims of Groups I-III should be grouped and examined together. All claims can be examined without serious burden because a search of the art for the claims of Group I should find art also relevant to the claims of Groups II-III. Hence, reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

The election of species is also made with traverse, as a search for art relevant to the elected species should find art also relevant to all of the other species. Hence, Applicants request rejoinder and examination of all of the species together as so doing would not create an undue burden on the Examiner.

Even assuming, *arguendo*, that the species lack unity of invention, Applicants are entitled to have at least ten sequences searched in the present application. The U.S. Patent and Trademark Office has implemented the following policy with respect to Unity of Invention concerning sequences:

The USPTO has decided *sua sponte* to partially waive 37 CFR 1.475 and 1.499 *et seq.* to permit applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature without the payment of an additional fee.

See MPEP § 1850. Therefore, Applicants are entitled to have at least ten sequences searched in the present application without division.

This traversal of the Restriction and Election of Species requirements should not be construed as a statement or an admission that the various groups and/or species identified by the Examiner are or are not patentably distinct. Instead, Applicants respectfully contend that the search required to examine all pending claims will not impose serious burdens on the Examiner. Imposition of a serious burden without restriction is a requirement for a proper restriction requirement and election of species requirement. See 37 C.F.R. § 1.141(a); see also MPEP §§ 803 and 806.04(b).

Reconsideration and withdrawal of the Restriction Requirement and Election of Species Requirement, and consideration and allowance of all pending claims, are respectfully requested. Applicants reserve the right to have additional species considered in the event that a generic claim is found to be allowable in accordance with 37 C.F.R. § 1.141(a).

Additionally, the Examiner has made an apparent rejection of the invention as a whole under 35 U.S.C. § 103 as being unpatentable over Kozlovksa *et al.* in view of Krieg *et al.* (See Office Action at page 4). Applicants respectfully traverse this rejection as premature and erroneously based on a reference not yet made of record in this application. In general, in an application when only a nonfinal written requirement to restrict is made, no action on the merits is given. See MPEP § 810. Thus, Applicants believe this rejection is improper and thus should be removed by the Examiner.

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It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono Attorney for Applicants Registration No. 42,473

Date: March 9, 2007

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